UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

JAMES W. NOLEN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 3:19-cv-0799**
	)	**Judge Aleta A. Trauger**
C.R. BARD INCORPORATED and BARD PERIPHERAL VASCULAR INCORPORATED,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM & ORDER

The parties have filed various motions in limine, several of which address the evidence and argument that may be presented at trial related to the actions of the Food and Drug Administration ("FDA"). As relevant to this Memorandum and Order, the defendants have filed a Motion in Limine No. 4 to Exclude Testimony and Evidence of FDA Warning Letter (Doc No. 114), to which plaintiff James W. Nolen has filed a Response (Doc. No. 158). Nolen has filed a Motion in Limine No. 2 to Preclude References to the Clearance of Bard IVC Filters by the FDA and Lack of FDA Enforcement Action as Proof of Safety and Efficacy (Doc. No. 124), to which the defendants have filed a Response (Doc. No. 161). For the reasons set out herein, the defendants' motion will be granted in part and denied in part and Nolen's motion will be denied.

This case involves the decision to treat Nolen with the implantation of the defendants' Meridian Filter, a small, ostensibly retrievable barrier intended to be inserted into the inferior vena cava ("IVC") in order to intercept blood clots before a clot can reach the lungs and cause a pulmonary embolism. As a prescription medical device, the Meridian Filter is subject to "[t]he Medical Device Amendments of 1976 ('MDA'), 21 U.S.C. §§ 360c–360k, 379–379a, [which]

establish[] the framework for federal regulation of medical devices. As amended, the MDA requires the FDA to place a device into one of three classes reflecting different levels of regulation." *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1003 (7th Cir. 2020). Meridian is a Class II device and was approved by the FDA as "substantially equivalent" to a previously approved device, through what is known as the agency's § 510(k) process. *See id.* (discussing § 510(k) process). Because the Meridian Filter received § 510(k) clearance, it was not subject to the "rigorous" standards of the FDA's "'premarket approval,' or 'PMA' process," which is reserved for new Class III medical devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

Both Nolen and the defendants seek to limit the information that the jury will receive about the defendants' dealings with the FDA. Specifically, the defendants ask the court to exclude any evidence or discussion related to "Topics 1, 2, 4, 5, 6, 7, and 8 of a July 13, 2015 FDA Warning Letter [as] irrelevant and inadmissible" and to reserve ruling on Topic 3 of that letter until trial. (Doc. No. 114 at 1.) Nolen asks the court to bar "any reference to 1) clearance of Bard IVC filters by the FDA, and/or 2) lack of FDA enforcement action regarding same constituting proof of safety and/or efficacy." (Doc. No. 124 at 1.)

These or similar issues were already addressed, in significant part, by Judge Campbell in the District of Arizona prior to bellwether trials in the multidistrict litigation ("MDL"), of which this case was part. *See In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00263-PHX-DGC, 2019 WL 1880029, at *6 (D. Ariz. Apr. 26, 2019); *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00474-PHX-DGC, 2018 WL 1109554, at *3 (D. Ariz. Mar. 1, 2018); *In re Bard IVC Filters Prod. Liab. Litig.*, 289 F. Supp. 3d 1045, 1049 (D. Ariz. 2018). Aspects of Judge Campbell's holdings were dependent on the specific allegations at issue in those cases. Generally speaking, however, Judge Campbell allowed the presentation of evidence related to the defendants' dealings

with the FDA if relevant to the product at issue, but he did exclude some material as irrelevant. This court will consider these motions in light of any issues unique to this case that might call for a different conclusion.

Warning Letter

On July 13, 2015, the FDA sent Bard a Warning Letter raising eight numbered concerns about actions taken by Bard. (Doc. No. 116-1.) Judge Campbell concluded that "[m]any topics in the warning letter lack probative value" but that the relevance of other topics covered by the letter depended on facts that would be revealed at trial. *In re Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 1109554, at *3. In this case, the parties have already stipulated that "they will not make any reference, solicit testimony, or seek to introduce at trial evidence concerning Topics 1, 2, 4, 5, 6, 7, and 8 of the Warning Letter." (Doc. No. 98 at 4.) Accordingly, the only contested portion of the motion in limine is whether the court should expressly reserve, until trial, its ruling regarding the admissibility of Topic 3 and require Nolen to specially raise the issue with the court, outside the presence of the jury, before he attempts to introduce such evidence. The defendants argue that, by doing so, the court would be following the same path taken by Judge Campbell in the bellwether trials, in which he excluded most of the letter's topics but ultimately decided, at trial, to allow discussion of Topic 3. The defendants explain that they are taking the somewhat unusual step of seeking a pretrial ruling that an issue *will not* be resolved pretrial, because they believe that Nolen's counsel intends to discuss Topic 3 in his opening statement. (*See* Doc. No. 115 at 3.)

Topic 3 involves the FDA's findings of regulatory violations arising out of Bard's "[f]ailure to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820. 198(a)." (Doc. No. 116-1 at 4.) Nolen argues that "Bard's post-market surveillance communications with the FDA are relevant to the question of whether Bard acted

reasonably for purposes of the negligent design claim," as well as Nolen's efforts to "refute Defendants' Comment k[1] defense." (Doc. No. 158 at 4.) The defendants respond that the specific failings addressed by Topic 3 either involved filters that were not the Meridian or involved unidentified filters that have not been shown to be the Meridian. As Nolen points out, however, the Meridian's clearance for sale was specifically premised on its similarity to other, preexisting filters, and the evolving filter designs used by Bard in its various models were frequently built on refinements of each other. It therefore seems very plausible that discussion of Topic 3 will be relevant. Indeed, as Nolen points out and as the court will discuss in the next section, the defendants themselves have insisted that, in order to fully tell the story of Bard's actions, the defendants must be able to discuss its history with the FDA. It would make little sense to allow the defendants to only present the portions of that history that reflect well on Bard.

That said, the court of course cannot know, at this stage, exactly what Nolen will say about the Warning Letter, and, for that reason, the court will not preclude the defendants from raising any objections to any particular characterization or admission into evidence at trial. The court's ruling, however, should not be taken as an endorsement of the defendants' ultimate arguments regarding Topic 3 or as an indication that the court expects to grant any motion to exclude discussion of Topic 3 at trial. The court, moreover, sees no reason to grant the defendants' request to require Nolen to seek the court's permission at trial before broaching the topic of the Warning Letter. The defendants' own motions indicate that they anticipate putting FDA compliance

[1] While strict liability usually attaches to manufacturers of defective or unreasonably dangerous products for the injuries caused thereby, Tennessee courts have recognized that Comment k to the Restatement (Second) of Torts § 402A creates an exception for "unavoidably unsafe products," if certain conditions are met. *Harwell v. Am. Med. Sys., Inc.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428–29 (Tenn. 1994). Pursuant to Comment k, an action does not lie against the manufacturer of such a product if the product was "properly prepared and accompanied by proper directions and warning." *Pittman*, 890 S.W.2d at 428–29; Restatement (Second) of Torts, Section 402A, cmt. k.

squarely at issue in this case and arguing that their actions must be understood in the context of the FDA's approach to IVC filters. While Topic 3 of the Warning Letter may not be expressly directed at the Meridian Filter itself, it does bear on the question of how the jury should construe the FDA's approach to Bard's IVC filters as a whole, as well as the adequacy of Bard's system for tracking complaints related to the filters. Moreover, evidence that Bard did a poor job, in general, of tracking IVC filter failures could tend to show that it was not acting reasonably when it designed new filters in light of its past experiences. The court, accordingly, will grant the defendants' motion only as to the exclusion of discussion of the topics other than Topic 3.

References to FDA Clearance

Nolen and the defendants agree that § 510(k) clearance review for a Class II medical device is less rigorous than full PMA review for a Class III medical device. The parties also appear to agree that obtaining § 510(k) clearance does not, as a matter of law, categorically preclude a state-law finding that a product had a defect in its design or labeling. Nolen, however, argues that the defendants plan to "assert an 'FDA defense' by implying that the FDA 510(k) clearance to sell its IVC filters demonstrates: (1) filter safety and effectiveness; and (2) Bard's reasonable conduct as a manufacturer." (Doc. No. 125 at 4–5.) In order to prevent such an argument, Nolen suggests that the court should exclude any reference to, or evidence of, the fact that the Meridian Filter received § 510(k) clearance *at all* and forbid the defendants from providing evidence of, or referencing, the FDA's lack of enforcement actions against Bard. (*Id.* at 10.)

The defendants argue that this issue was adequately addressed by Judge Campbell in relation to the bellwether trials, when, for example, he ruled as follows pursuant to Georgia law:

> Georgia courts have adopted a risk-utility analysis for design defect claims like those asserted by [the plaintiff]. This analysis incorporates negligence principles and the "concept of 'reasonableness,' i.e., whether the manufacturer acted reasonably in choosing a particular product design[.]" One of the many factors a

> jury may consider in its reasonableness determination is the manufacturer's compliance with federal regulations. Compliance with the regulations may not render a manufacturer's design choice immune from liability, but it can be a "piece of the evidentiary puzzle." Given these principles of Georgia law, the Court finds that evidence of Bard's compliance with the 510(k) process, while certainly not dispositive, is nonetheless relevant to the reasonableness of Bard's conduct and whether the company defectively designed the G2 filter.

In re Bard IVC Filters Prod. Liab. Litig., 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018) (citations omitted); *see also Keen v. C. R. Bard, Inc.*, 480 F. Supp. 3d 646, 650-51 (E.D. Pa. 2020) (adopting similar argument post-remand).

Nolen has not identified any principle of Tennessee law that would mandate a different conclusion. To the contrary, "[i]n Tennessee, a party . . . may introduce proof of its compliance with federal regulations to demonstrate that it has satisfied its standard of care." *Lake v. Memphis Landsmen, LLC*, No. W2011-00660-COA-RMCV, 2014 WL 895519, at *9 (Tenn. Ct. App. Mar. 7, 2014) (citing *Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 536 (Tenn. 2008)). The Tennessee General Assembly has expressly provided that "[c]ompliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, *shall raise a rebuttable presumption* that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards." Tenn. Code Ann. § 29-28-104(a) (emphasis added). Compliance with FDA regulations, therefore, is plainly relevant to Nolen's claims under Tennessee law. Similarly, while there are many reasons why an agency might fail to commence enforcement actions against a company, the lack of enforcement actions is still relevant to the question of its compliance.

Nolen devotes most of his briefing to emphasizing the limited scope of § 510(k) clearance review. Those arguments, however, are ones he can make at trial—just like the defendants will

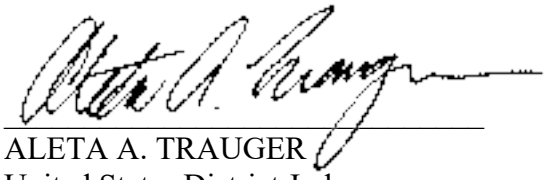
make their own arguments about how the jury should construe the FDA's actions in the context of the § 510(k) process. The court, moreover, is skeptical that the facts of this case could be accurately relayed to the jury in an intelligible manner *without* addressing the role of the FDA. (*See* Doc. No. 176-1 (May 24, 2021 Western District of Wisconsin Order) at 29 (noting that "a brief explanation of the 510(k) process may help the jury understand the relationship between the Recovery, Meridian, and other filters").) Regardless of whether one has faith in any particular aspect of the FDA's process, the reality is still that the medical device field is heavily regulated and that those regulations provide the backdrop for actions taken by companies that manufacture and sell those devices. It is difficult to imagine how one could tell a full, accurate, and understandable story of the marketing of any medical device without discussion of the FDA review process. The court, accordingly, will not erect an artificial barrier around the facts related to the FDA's review and regulation of the Meridian Filter.

The court's ruling should not, of course, be construed as granting the defendants free rein to argue whatever they would like about the meaning of the FDA's granting clearance or not taking enforcement actions. If, for example, the defendants were to argue that § 510(k) clearance represented a determination that the Meridian filter itself had been demonstrated to be safe and effective, as opposed to merely substantially equivalent to another approved device, then Nolen could persuasively object, because that is simply not a fair characterization of what § 510(k) review constitutes. The broad exclusion that he requests, however, is unsupported by Tennessee law. The court, therefore, will deny his motion.

For the foregoing reasons, the defendants' Motion in Limine No. 4 to Exclude Testimony and Evidence of FDA Warning Letter (Doc No. 114) is hereby **GRANTED** in part and **DENIED** in part, and Nolen's Motion in Limine No. 2 to Preclude References to the Clearance of Bard IVC

Filters by the FDA and Lack of FDA Enforcement Action as Proof of Safety and Efficacy (Doc. No. 124) is hereby **DENIED**. It is hereby **ORDERED** that no party shall make any reference to, solicit testimony about, or seek to introduce at trial evidence concerning Topics 1, 2, 4, 5, 6, 7, and 8 of the FDA's March 13, 2015 Warning Letter. Nolen may introduce evidence related to Topic 3 of the Warning Letter without seeking prior permission of the court outside the presence of the jury, subject to any additional objection that the defendants raise to the specific use being made of Topic 3 at the time.

It is so **ORDERED**.



ALETA A. TRAUGER
United States District Judge